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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,832	10/13/2001	Kelly B. Smith	1006.F-5489 CIP 1	2307

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 10/20/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,832

Applicant(s)

SMITH ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 14-17 is/are allowed.
- 6) ☒ Claim(s) 1 & 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Applicant's amendment filed August 4th, 2003 amended claims 1 & 12; cancelled claims 2 & 13; and made amendments to the specification to correct informalities. The examiner also thanks applicant for re-submitted the duplicate set of formal drawings with the amendment; the drawings have been entered in the case.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 3-11 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Giesler et al. ('708) in view of Bormann et al. (5,738,796).

Giesler et al. (hereafter Giesler) discloses a blood processing system having a blood draw tube (cell source), a separation element for separating the whole blood into its components, a pump station wherein the pump is in communication with the tubes, and a controller that controls the operation of the pump such that it operates in multiple modes. The system includes an additive solution (saline, see fig. 1 bag 50) for delivery to the cassette channel for priming. The saline is added as needed. Further, the system includes a cassette body that incorporates the tubing of the pump and blood components tubing. The pump has multiple pumping stations and valves for directing fluid flow throughout the cassette. The pump directs whole blood from the donor access to the separation element for separating wherein the components are red blood cells and plasma. After separation of the whole blood into components, the pump directs the separated components into their respective storage containers. Giesler also teaches that a leukocyte filter may be placed in-line with the tubing to filter out leukocytes from the platelet rich plasma (PRP). The centrifuge assembly also is disclosed to include a processing controller (246) that governs the operation of the centrifuge assembly. The processing controller includes an integrated input/output terminal (248, also seen on fig. 1), which receives and display information relating to the processing procedure. The controller also governs the operation of each control station, the cassettes and the operation of the valve and pump modules to convey fluids through the cassettes to achieve the objectives of the system and treatment

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protocol. Giesler discloses that the controller is a processing controller that governs all of the operating functions of the system. Therefore, with respect to the controller operating the pump in alternating first and second modes to convey solutions, it would be obvious to one having skill in the art to program the controller of Giesler according to desired or optimum functions of the protocol desired since it has been held that discovering the optimum or workable ranges (i.e. modes of use) involves only routine skill in the art.

Giesler discloses the invention as claimed, however does not teach of using an in-line leukocyte filter in the component collection channel to remove leukocytes from red blood cells or where the filter is a fibrous medium in a housing.

Bormann et al. (hereafter Bormann) discloses a system and method for separating whole blood into its components and further separating leukocytes from the separated components in procedures such as apheresis. After separation, the separated component is passed through a leukocyte depleting filter before it is stored in its storage container. It is desirable to remove as many leukocytes from separated plasma or red blood cells since leukocytes can cause undesirable effects when administered to another patient.

It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have modified the system of Giesler to include a leukocyte filter in one of the component transfer lines since it is desirable to remove as many leukocytes from separated plasma or red blood cells to prevent any undesirable effects when administering the separated plasma or cells to another patient.

Allowabl Subject Matter

Claims 12 & 14-17 are allowed. The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the method including step (c) which recites repeatedly alternating steps (a) and (b) according to a pre-established pumping sequence to mix additive with blood cells at a constant ratio in combination with the other steps in the claims.

Response to Arguments

Applicant's arguments filed August 4th, 2003 have been fully considered but they are not persuasive with respect to claims 1 & 3-11. As stated in the rejection above, the system of Giesler et al. includes a controller that governs all components and aspects of the operation of the centrifuge assembly. The controller also governs the operation of each control station, the cassettes and the operation of the valve and pump modules to convey fluids through the cassettes to achieve the objectives of the system and treatment protocol. Giesler discloses that the controller is a processing controller that governs all of the operating functions of the system including operation of the pumps and, if desired, according to a desired or optimum functions set forth for in the protocol. Giesler also teaches that an additive (saline) is delivered to cassette and further conveyed from the cassette into the processing chamber. Thus, the controller of Giesler may function as required to deliver saline to the processing chamber according to a preset ratio, since delivering saline is a functions of the system that will be monitored and controlled by the controller of the system of Giesler.

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Therefore, it is the position of the examiner that the controller of Giesler is capable of operating the pump in alternating first and second modes to convey solutions, such as saline, according to a stored protocol. The modifications of the controller Giesler would be made to protocols if it were desirable to have an additive supplied.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

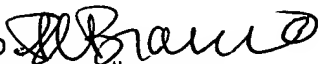
Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone

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number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and for After Final communications.

Tricia Bianco
Patent Examiner
Art Unit 3762

tmb 
October 16th, 2003